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Guidance for Industry

STABILITY TESTING FOR MEDICATED PREMIXES

DRAFT GUIDANCE

This guidance document is an annex to the parent guidance VICH GL3, "Stability Testing of New Animal Drug Substances and Products in the Veterinary Field". It addresses the recommendations for stability testing of new veterinary medicinal Medicated Premix products intended for submission for approval to the European Union, Japan and the United States.

This guidance represents current thinking and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.

Comments and suggestions regarding the document should be submitted to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 99D-2249.

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STABILITY TESTING FOR MEDICATED PREMIXES

Recommended for Consultation
at Step 4 of the VICH Process
on 22 October 1998
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STABILITY TESTING
FOR MEDICATED PREMIXES

Endorsed by the VICH Steering Committee at Step 3 of the VICH Process

22 October 1998

1. General

The VICH Harmonized Tripartite Guidance covering the Stability Testing of New Drug Substances and Products in the Veterinary Field (hereafter referred to as the parent guidance) references an annex for Medicated Premixes. This document is an annex to the parent guidance and addresses the recommendations for stability testing of veterinary medicinal Medicated Premix drug products. The parent guidance (VICH GL3) provides a general indication of the information on product stability generated, but the annex for Medicated Premixes leaves sufficient flexibility to encompass a variety of different practical and scientific considerations that are specific to the characteristics of the drug products being evaluated. Other stability studies which might be important to consider like stability in relation to conditioning and pelleting, segregation and homogeneity studies are not within the scope of this guidance.

2. Preamble

The guidance primarily addresses the generation of acceptable stability information for submission in Registration Applications for medicated premix drug products containing new molecular entities. Medicated Premixes are intended for oral administration following incorporation into animal feed. The guidance only pertains to Medicated Premixes, and does not currently seek to cover information required for products manufactured from medicated premixes. Stability studies carried out with a medicated premix should be in line with the parent guidance. However, the application of the parent guidance may be limited in some instances. This guidance therefore describes those areas where there may be differences in the stability data package for medicated premixes.

3. Storage Test Conditions and Test Parameters

Medicated Premixes are recommended to be tested at 25°C ± 2°C / 60% RH ± 5% (long-term testing) and 40°C ± 2°C / 75% RH ± 5% (accelerated testing) and with the same schedule intervals as described in the Parent Guidance for drug product. Other storage conditions are allowable if

justified. Where "significant change" occurs due to accelerated testing, additional testing at an intermediate condition e.g., 30°C ± 2°C / 60% RH ± 5% should be conducted. "Significant change" at the accelerated condition is defined as failure to meet specifications. Evidence is necessary to demonstrate the stability of the Medicated Premix before incorporation into an additional feed. The shelf-life specification of a Medicated Premix should include necessary stability indicating test parameters.

4. Packaging Materials

The testing should be carried out in the final packaging proposed for marketing when practicable. The use of smaller comparable containers simulating the actual market packaging may be justified.

5. Glossary

Carrier - An edible material to which drug substances are added to facilitate uniform incorporation into feed.

Medicated Premix (Type A Medicated Article) - A Medicated Premix is a veterinary medicinal product consisting of a mixture of one or more drug substances, generally with a carrier, that is prepared to facilitate oral administration of the drug to animals when mixed with feed.

For additional definitions, please refer to regional guidance or regulations.